

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Nesbitt on January 21, 2010.

Claims 3-4 and 12 were canceled.

Claim 5 was amended as follows:

- 5. (currently amended) A method for measuring total dietary fat absorption by the digestive tract of a subject, useful for diagnostic testing for diagnosing malabsorption of dietary fat by the digestive tract of the subject, and impairment of dietary fat digestion in the subject, comprising the steps of:
- a. providing a test meal for consumption, comprising a predetermined amount of dietary fat and a predetermined amount of a marker consisting of sucrose polyester comprising sucrose behenate,
 - b. administering ingestion of the provided test meal by a subject under diagnosis for malabsorption of dietary fat by the digestive tract of the subject or an impairment of dietary fat digestion in the subject,
 - c. analyzing for the amount of total fatty acid in the dietary fat and the amount of behenic acid in the sucrose polyester recovered in ~~collecting~~ a sample portion of fecal matter collected from the stool of the subject at an interval following ingestion of the provided ~~said~~ test meal wherein the sample portion does not result from the homogenization of an entire stool collected from the subject, and

- d. ~~analyzing for the amount of total fatty acid in the dietary fat and the amount of behenic acid in the sucrose polyester recovered in the sample portion, and~~
- e. ~~calculating the amount of dietary fat recovered from the provided test meal based on the analyzed amounts of total fatty acid and behenic acid, to determine the amount of dietary fat that was absorbed by the digestive tract of the subject.--~~

Claim 8 was amended as follows:

--8. (currently amended) The method according to Claim 5 wherein ~~the collecting step comprises collecting the sample portion of the fecal matter is collected during the day following ingestion of said test meal, or during each of the two consecutive days following ingestion of the provided test meal.--~~

Claim 9 was amended as follows:

--9. (currently amended) The method according to Claim 5 wherein the provided test meal further comprises a colorant, in an amount ~~a quantity~~ sufficient to change the color of the fecal matter produced from the provided test meal, such that the sample portion collected from the subject is colored according to the colorant used.--

Claim 19 was amended as follows:

--19. (currently amended) The method according to Claim 18 wherein the provided test meal further comprises a colorant, in an amount ~~a quantity~~ sufficient to change the color of the fecal matter produced from the provided test meal, such that the sample portion collected from the subject is colored according to the colorant used.--

New claims 23-28 were added as follows:

--23. (new) The method of Claim 5 wherein the step of analyzing comprises i) collecting a sample portion of fecal matter from the stool of the subject at an interval following ingestion of said test meal wherein the sample portion does not result from the homogenization of an entire stool collected from the subject, and ii) analyzing for the amount of total fatty acid in

the dietary fat and the amount of behenic acid in the sucrose polyester recovered in the sample portion.

24. (new) The method according to Claim 5 wherein the provided test meal comprises 0.1% to 10% sucrose behenate by weight of the dietary fat.

25. (new) The method according to Claim 6 wherein the provided test meal comprises 0.1% to 10% sucrose behenate by weight of the dietary fat.

26. (new) The method according to Claim 6 wherein the amount of the collected fecal sample portion is from about 10 milligrams to about 2 grams

27. (new) The method according to Claim 26 wherein the amount of the collected fecal sample portion is from about 10 milligrams to about 20 milligrams

28. (new) The method according to Claim 27 wherein the provided test meal further comprises a colorant, in an amount sufficient to change the color of the fecal matter produced from the provided test meal, such that the sample portion collected from the subject is colored according to the colorant used. --

2. The following is an examiner's statement of reasons for allowance: Application serial no. 10/567,143 is being allowed in view of the persuasive declaration filed under 37 CFR 1.132 on October 16, 2009, and since none of the prior art of record teaches or fairly suggests a method for measuring total dietary fat absorption by the digestive tract of a subject comprising the steps of providing a test meal for consumption to a subject, wherein the test meal comprises a predetermined amount of dietary fat and a predetermined amount of a marker consisting of sucrose polyester comprising sucrose behenate, administering ingestion of the test meal to the

subject, collecting a sample portion of fecal matter from a stool of the subject collected at an interval following ingestion of the test meal, wherein the sample portion does not result from homogenization of an entire stool collected from the subject, analyzing for the amount of total fatty acid in the dietary fat and the amount of behenic acid in the sucrose polyester recovered in the collected sample portion of fecal matter, and calculating the amount of dietary fat recovered from the test meal based on the analyzed amounts of total fatty acid and behenic acid to determine the amount of dietary fat that was absorbed by the digestive tract of the subject.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim, can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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mmw

January 22, 2010

/Maureen M. Wallenhorst/

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